MICHIGAN ENVIRONMENTAL SCIENCE BOARD

AIR PANEL
MEETING SUMMARY
FRIDAY, APRIL 18, 1997
PARK INN INTERNATIONAL
HOWELL, MICHIGAN

PANEL MEMBERS PRESENT

Dr. Lawrence Fischer, Chair
Dr. Raymond Demers (via speaker-phone)
Dr. Jack Harkema
Dr. Ralph Kummler
Dr. Ken Rosenman
Dr. George Wolff
Mr. Keith Harrison, Executive Director

DMB/EAD SUPPORT STAFF PRESENT

Mr. Jesse Harrold, Environmental Officer
Ms. Patricia Hiner, Secretary

I. CALL TO ORDER

Dr. Lawrence Fischer called the meeting to order at 9:00 am.

II. EXECUTIVE DIRECTOR'S REPORT

Mr. Harrison indicated that the March meeting summary could not be completed prior to the April meeting since, under the new state contract for the stenographer, staff no longer are able to receive the transcripts as quickly as before. Mr. Harrison made available to the Panel a disk with a copy of the full transcript. Mr. Harrison stated that the Panel meeting packages contained a copy of the requested Abbey studies and a 1995 paper on iron toxicity by Dr. A.E. Aust. Dr. Aust has promised additional information, but it had not yet arrived. Mr. Harrison indicated that the Michigan Department of Environmental Quality has submitted comments to the U.S. Environmental Protection Agency (USEPA). Copies of the comments will be provided to the Panel.

III. PANEL DISCUSSION

Dr. Fischer reviewed the Governor's original charge to the Panel, which was in the November 21, 1997 letter. In the letter the Panel was asked to evaluate the air quality and human health assumptions, interpretations and conclusions in the Natural Resources Defense Council (NRDC) report. There was consensus that the Panel's report would need to go beyond that, since the issues were broader than that report alone, and since more information has become available since that report was written.

The Panel will include in its review all the scientific information relative the air quality/human health issue.

The second charge was to identify and evaluate the appropriateness of the methodology used to develop the NRDC estimates of mortality and determine whether there was sufficient evidence to attribute causality. According to Dr. Wolff, there has been some confusion about the mortality estimates from expert to expert, and also about the difference between daily and annual mortality estimates. The NRDC estimate was 64,000 annual premature deaths. The USEPA used the Pope study to justify the standard it used in its regulatory impact analysis and to calculate the number of premature deaths (20,000) it would avoid with the adoption of the new standards. However, an outside consultant, Dr. Kay Jones, discovered that the Pope study had confused the median for mean value and that the USEPA subsequently used the median, which is about 25 percent lower than the mean. Consequently, the USEPA has had to revise the estimate downward 25 percent, from 20,000 premature lives to 15,000 premature lives. The USEPA had argued that there is a threshold at 15 $\mu g/M^3$. When that was modified by the 25 percent, it was 18.75 $\mu g/M^3$. Only ten cities had means greater than 18.75 $\mu g/M^3$, so the mortality estimate was forced even lower, from 15,000 premature deaths to less than 1,000 premature deaths. The USEPA may now be considering basing its estimates on the Six City study rather than the Pope study.

Dr. Rosenman asked whether the Panel should look at causation as a separate issue, since if there is no proven effect, there is no need to seek a cause. He indicated that the evidence does suggest that there is something causing premature deaths, but wondered whether it could be found and whether that was within the Panel's charge or not. Dr. Wolff suggested that the Panel needs to go further and separate out the cross-sectional studies which suggest premature mortality and address that issue in two questions: is there causality, and is the outcome real. There does seem to be a relationship between the daily PM values and daily mortality which also needs to be addressed. There are approximately 20 studies that suggest a relationship to daily mortality. Dr. Kummler agreed that there were two separate issues. But it may be possible to hypothesize a better connection between long-term averages and the community measures and personal dosage than with daily exposures and the community PM measures. Dr. Rosenman thought it was really one issue, but different methodological approaches. In one case, cites are compared at the same time. In another case, the object of analysis is a city over time. There are also morbidity studies to consider. When evaluating biological plausibility, morbidity studies have to be considered. They are just different methodologies addressing the same issue. The total picture should be reviewed, not just the separate components - cross-sectional mortality studies, time series mortality studies, time series morbidity studies, etc. Dr. Kummler suggested that different end points might have different cause and effect relationships, which have to be taken into account. Dr. Rosenman responded that most of the studies talk about cardiorespiratory disease, so the end points are not different. They may be measured differently when studying morbidity and when studying mortality, but they are the same organ system. Dr. Wolff reiterated that there has to be some separation of issues because the data on the daily studies are different from

those in the cross-sectional studies. Dr. Harkema agreed that there is more weight to the relationship between daily mortality and air quality than there is to the cross-sectional studies showing differences among cities.

Dr. Fischer went on to discuss the ozone issue addressed in the Governor's second letter. The Panel has not substantially addressed ozone. Dr. Kummler suggested that the Panel look to the USEPA Clean Air Scientific Advisory Committee (CASAC) statement on ozone. Dr. Wolff said that CASAC stated that there was no difference in the degree of protection among the standards. The USEPA actually attributes all premature mortality to PM rather than to ozone.

Dr. Demers explained that he and Dr. Rosenman have been focusing more on the general issue of causality based on the epidemiological studies than on specifics, like the number of premature deaths to be expected in Michigan, etc. Causality and evidence on health issues should be addressed as two different issues. Dr. Rosenman agreed that there are indeed two issues, but in the sense that if causality is accepted, and if there are risk estimates in any range, the next decision is whether the risk estimates are reasonable. If causality is not accepted, there is no point in addressing the validity of the risk estimates. However, Dr. Demers pointed out, causality is not going to be a black and white issue. Dr. Fischer indicated that that is why he would like to have the issues addressed separately.

Dr. Kummler asked whether the Panel could agree that there are premature deaths, observable, quantifiable health end points, regardless of cause, that should cause concern. One of the hypotheses is that particulate matter may actually be a surrogate for something else, lifestyle, for instance. Dr. Fischer suggested going further, and asking whether there was evidence that there are premature deaths and morbidity from any kind of air pollution. Dr. Wolff indicated that there was no question that there have been health outcomes historically from high levels of air pollution. The question is, is that the case today, with much lower concentrations. Dr. Demers agreed, and thought the Panel should look at total mortality and cause-specific mortality that may be attributable to the ranges of PM_{10} and $PM_{2.5}$ that are in the literature. Dr. Fischer questioned if there was sufficient epidemiological evidence to say that when the PM_{10} standard is exceeded there is a health outcome. Dr. Demers responded that he has never seen more consistency in epidemiological studies than in this literature. Dr. Wolff indicated that there are a lot of studies with consistent results, but most have been done by the same group. They have had to use a different form of the model in order to explain the data in each city or area. Dr. Demers stated that there are studies all around the world of various designs that find the same result. But, Dr. Wolff pointed out that the results are similar but not necessarily the same. In addition, two of the three cohort studies were done by the Harvard group, Schwartz and Dockery. Most of the ecological studies were done by Lipfert, who has already indicated to the Panel that he no longer believes his earlier studies. Dr. Rosenman said that results are often questioned if the same data are used over and over, but not usually because of the same investigators, who are using different data sets. Dr. Wolff stated that Joel Schwartz described it as an iterative procedure; data are taken from a certain area and

manipulated, trying different combinations of variables, different lag times, different averaging times, until they get the results they want, in an attempt to maximize the relationship between PM and mortality. Dr. Demers questioned if Dr. Wolff was misstating the case, that trying to get a model to fit the data is not the same as trying to get the data to go in the direction the researchers want. Dr. Wolff indicated that different models and correlations were used in each city. They have not used the same methodology between cities, the stated reason being that composition of the PM is different in the different areas.

Dr. Fischer asked Dr. Rosenman and Dr. Demers to look at each of the epidemiological studies and critique each from a scientific point of view, giving each a rating and indicating where its strengths and weaknesses are. Dr. Rosenman indicated that that is not the way epidemiologists typically address such issues. They have seven criteria they use to determine causality. Epidemiology is not like a laboratory experiment, where all extraneous variables can be controlled. They all have methodological problems; the test is whether they fit across a consistency. The seven criteria will assess how well any parameter, like dose-response is substantiated. Dr. Fischer said he would still like to have some sort of weight put on each individual study's value.

Dr. Kummler added one qualitative criterion to the work Drs. Rosenman and Demers will be doing for the Panel. He would like the epidemiology to be "robust", with results able to stand even with additional variables. Dr. Demers agreed. Dr. Rosenman added that it is usually not possible to go back and add new variables once a study is published; but the 50 epidemiological studies on particulate matter published in the past ten years have been peer reviewed. With that many studies, especially when they are reasonably consistent in the same direction, and cover a lot of geography, there is a sense of how other variables were controlled for; looking at the cluster of studies as a whole, and not individual ones, is most useful. Dr. Wolff stated that one of the studies done in Birmingham, Alabama was reanalyzed adding humidity and the relationship between PM and mortality disappeared entirely . Several other of the studies have been re-evaluated and other explanations found to fit equally well or have shown no actual relationship between mortality and PM.

Dr. Demers asked whether the Panel could agree that the actual constituent of particulate matter that may be responsible for morbidity and mortality outcomes is unknown, and that whatever it is, it is likely to vary from location to location. Dr. Wolff could not agree, because that statement assumes causality.

Dr. Rosenman proposed the agreement that the epidemiological studies currently under consideration show variation in mortality between cities and over time and that there is a distinct health problem. There was agreement to that.
Dr. Demers asked if there was agreement that at certain higher levels than those currently being discussed particulate matter does cause excess mortality. Dr. Wolff agreed that at high concentrations, historical cases can be cited and there was general agreement.

Dr. Demers asked whether there was agreement that there is no obvious threshold effect in the relationship between PM and mortality or morbidity. Dr. Wolff expressed two concerns with that statement. First, many of the studies make the assumption that there was a linear relationship down to background, so they are incapable of making that distinction, and second, there are too many errors and uncertainties associated with the data, so that the data are not capable of detecting a threshold. Dr. Demers replied that epidemiological studies rarely show evidence of a threshold response, since extraneous variables cannot be controlled for as well as in laboratory studies. Dr. Fischer agreed, adding that there is evidence that very sensitive people are the victims of the adverse health effects, for example, people with compromised lung function. Given the spectrum of sensitivity within the population, to detect a threshold is almost impossible. Dr. Demers asked if the Panel could agree that there is no apparent threshold because of the spectrum of sensitivities within the human population. Both Mr. Harrison and Dr. Rosenman questioned the relevance of the statement. Dr. Demers answered that if there is no easily defined threshold, the policy decision becomes a more complicated matter of deciding the terms of a trade-off between an acceptable level of negative effects and monetary costs of control, rather than an obvious cutoff. Dr. Rosenman said that generally in these kinds of studies, it is hard to show an effect at lower doses, because there is too much “noise”.

Dr. Rosenman asked whether the Panel could agree that the differences in mortality found in the more recent epidemiological studies at lower levels of PM have something to do with some air or meteorological phenomena, as opposed to, say, lifestyle factors. Neither Dr. Wolff nor Dr. Kummler could agree with the statement. Dr. Kummler indicated that there was too much uncertainty in every point of the chain of causation - from the difficulty in measuring individual exposure, to the effect of time spent inside and the quality of inside air, to the actual dosage that gets to an organ. There are other things that may be better correlated, including lifestyle. Dr. Wolff stated that lifestyle is only an issue with cohort studies, not with the daily morality. Dr. Rosenman indicated that the cross-sectional studies controlled fairly well for the lifestyle habits that are thought to affect mortality. Dr. Wolff disagreed; saying that Dr. Lipfert showed that exercise explained the found mortality effects as well as anything. Drs. Rosenman and Demers said they would have to review Lipfert again to see whether they could accept that explanation. Dr. Demers asked that in the interest of time, Dr. Wolff review the articles and underline relevant sections prior to sending them to the rest of the Panel.

Mr. Harrison expressed concern that human lifetime is spent indoors and that the epidemiological studies that he has reviewed relied too much on assumption rather than on direct experimental evidence. Dr. Kummler expressed some concern for the indoor air problem but said there was no comparative measurement of the problem of indoor air exposure and outdoor air at the same time and place. Dr. Fischer questioned if an indoor-outdoor time allotment per affected patient has been considered in the studies. Dr. Rosenman answered that he did not recall any mortality studies that considered percentage of indoor-outdoor time exposure per individual case but the issue may have been considered in some morbidity studies. Dr. Kummler indicated that there have been number of studies where percentage of indoor-outdoor air was considered but the

number of confounders made those considerations futile.

Dr. Kummler questioned if indoor air where no smoking takes place should only be considered in the studies. Dr. Wolff replied that none of the investigators considered smoking and non-smoking indoor air in their studies. Dr. Rosenman stated that only a limited number of persons can be equipped with monitoring pumps during an indoor air study and that an assumption is made that the rest of the associated persons breath the same air. Dr. Wolff commented that results between central monitor and individual personal monitors findings are not consistent.

Dr. Fischer summarized that the Panel had agreed that inhaling particulates at high concentrations could cause morbidity and mortality and that there is a great spectrum of human sensitivity to airborne particulate matter. He asked if the Panel would also concur that a demonstrable cause and effect can be shown at high PM concentration and that a non-demonstrable effect occurs at lesser concentration. Dr. Wolff indicated that some postulate that the reason for the high mortality during the high PM concentration was the accompanying high concentration of acidic aerosols accompanying the high PM. The ammonia in the human system is probably enough to neutralize the acid aerosols commonly encountered on low PM days. Dr. Rosenman added that some individuals have underlying risk factors that may result in their being more sensitive to low levels of some air pollutants. Dr. Harkema related this to low levels of ozone elevation and the increased emergency room visits by asthmatic children.

Dr. Kummler questioned if the motivation for the new air standards was the result of noting some statistical health variants and then an attempt to associate something causal with them (e.g., PM). Dr. Rosenman responded that excess variation from the background motivates epidemiological study. Dr. Wolff indicated that cause and effect could be validated with the improved air quality today in the U.S. Dr. Fischer addressed the causality issue by asking if the chemicals associated with fine PM are the adverse health factors or are the factors unknown. All the Panel members concurred that the causal factor or factors are in question.

Dr. Demers questioned if the weather played a major part in all the excess mortality in all the studies. Dr. Wolff stated that half of the studies he was familiar with did consider weather as a factor in mortality and that weather should always be considered a factor in any mortality study. However the cohort studies, the Six City study and perhaps the Pope study, only treated the extremes of temperature, rather than controlling for weather in a systematic way.

Dr. Demers asked if there is more concern for $PM_{2.5}$ or PM_{10}. All the Panel members agreed that $PM_{2.5}$ is as big of a concern as PM_{10} because of its inhalabibity. Dr. Kummler added that the combustion generated $PM_{2.5}$ appeared more biologically active. Dr. Wolff stated that what the Panel should be looking for is biological plausibility. Dr. Rosenman brought up the point that the smoking issue was discredited early on because of a lack of biological plausibility but was later proven biologically. So he considers a statistical basis reason for biological plausibility and it must be realize that mortality is always the “tip of the iceberg” in epidemiological health affects evaluations.

Dr. Kummler expressed the need for a direct cause and effect to target a need and create an effective regulation. Dr. Rosenman replied that a causal relationship was adequate to justify intervention. Dr. Wolff stated that the PM in air has been decreasing at a rate of three percent a year from the 1970s and that no attempt has been made by USEPA or anyone else to relate this improvement to increased health benefits. It would be prudent to be assured that additional PM standards would result in real health benefits.

Dr. Wolff suggested that the epidemiological evaluation criteria be agreed upon by the Panel and then applied to the studies that were the basis of the proposed air regulations. Mr. Harrison said there was on other epidemiologist in British Columbia that the Panel may want to be involved in this process. Dr. Rosenman suggested that each study should be rated either yes, no or unknown in terms of meeting the criteria. Dr. Fischer asked Dr. Rosenman what his position was on reanalyzes. Dr. Rosenman replied that reanalysis was an extended critique that may employ different assumptions and any of them may provide some new ideas.

Dr. Fischer raised the question regarding the validity of the mortality estimates, which is a form of risk assessment. Dr. Rosenman indicated that the Panel needed the USEPA statement on the Pope paper and then Pope response. Dr. Kummler asked if the Pope error decreases the projected NRDC 60,000 deaths per year. Dr. Wolff answered that it decreases it also by a minimum of 25 percent. Dr. Rosenman asked where could the USEPA's method of risk assessment be found. Dr. Wolff answered that it could be found in the agency's regulatory impact analysis. The NRDC used totals as attributed to PM. The USEPA used actual levels of PM and may have used a delta calculation. Dr. Rosenman stated that the issue are, is there increased mortality from $PM_{2.5}$, is there a causal relationship and should the Panel use all the mortality studies regardless of methodology. The Panel needs review documents that include all the mortality studies related to PM. Dr. Wolff added that there are some recent review documents that should be reviewed also.

Dr. Fischer asked if iron is commonly found in PM. Dr. Wolff answered that almost any metal can be found in PM and that most are in an oxide form. Most metal containing PM is formed at high combustion temperatures.

Dr. Fischer discussed the Panel's of writing assignments. Dr. Demers and Dr. Rosenman would continue looking at causality between mortality and exposure to $PM_{2.5}$, the 30 plus existing mortality studies and risk estimates with the application of the epidemiological criteria. Dr. Wolff agreed to write on the contrasting points of view of the CASAC panel, provide both sides of the issues and their justifications and to evaluate the assumptions. Dr. Harkema will review the toxicology studies related to PM_{10}, ultra-fines and acid aerosols, the associated lung and cardiovascular effects and look at biological plausibility. Dr. Kummler handed in a draft of his portion of the report. Dr. Wolff asked Drs. Rosenman and Demers to evaluate the major studies to see how many of the seven or eight criteria deemed essential to a good epidemiological study

were met in these studies and the concluding results. Mr. Harrison was asked to put together all the introductory material and the draft response for the NRDC portion of the report. The response for Directive 3 was not assigned.

IV. PUBLIC COMMENTS

Mr. Leonard, Detroit Edison, suggested that Dr. Schwartz and Dr. Lipfert be requested to provide a short critique of the main studies as they apply to the epidemiological criteria.

V. NEXT MEETING DATE

No additional meetings were scheduled.

VI. ADJOURNMENT

The meeting was adjourned at 1:47 PM.

Respectfully submitted,
Keith G. Harrison, M.A., R.S., Cert. Ecol.
Executive Director
Michigan Environmental Science Board